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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/702,498	10/31/2000	Tsuyoshi Tokusumi	50026/025001	9833

21559 7590 05/20/2003

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER
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FOLEY, SHANON A

ART UNIT	PAPER NUMBER
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1648  
DATE MAILED: 05/20/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/702,498	TOKUSUMI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Shanon Foley	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 February 2003.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4,8,9 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,8,9 and 23-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Sequence Compliance***

Claim 24 is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. See 37 CFR § 1.821 (a)-(d) and MPEP § 2422. Specifically, a SEQ ID NO. is required to identify any nucleic acid sequence comprising ten or more nucleotides. It appears that the sequence contained within claim 24 is the RNA nucleic acid sequence of SEQ ID NO: 33. It is suggested that applicant recite SEQ ID NO: 33 and the corresponding DNA nucleotides in claim 24. The DNA sequence of SEQ ID NO: 33 is the sequence within the vector recited in claim 1 and would transcribe to a corresponding RNA nucleotide sequence.

***Claim Rejections - 35 USC § 102***

Claims 1-4, 8, 9 and 23-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hasan et al. (Journal of General Virology. 1997; 78: 2813-2820).

Claim 1 is drawn to a Sendai virus vector carrying a foreign gene that is positioned 5' to a viral gene within the vector, wherein an additional E-I-S sequence is present between the foreign gene and the viral gene flanking the foreign gene at the 5' or 3' end. Claim 2 specifies the location of the foreign gene. Claim 3 recites the gene order of the viral proteins: NP, P, M, F, HN and L. Claims 4, 8 and 9 are drawn to a vector carrying a DNA corresponding to the negative strand genomic RNA of claim 1. Claim 23 requires that the additional E-I-S sequence is located between the foreign gene and the 5'-flanking gene of a viral protein and claim 24 describes a nucleotide sequence of the E-I-S. Claim 25 is drawn to a composition comprising at least  $4.7 \times 10^8$  pfu/ml of the Sendai virus vector of claim 1 in a physiologically acceptable carrier.

Hasan et al. anticipate a recombinant Sendai virus vector that expresses the firefly luciferase gene between the N protein and the 5' end of the RNA genome. The recombinant Sendai virus genome is expressed in a DNA expression vector, see Figure 1 on page 2815. Hasan et al. also anticipate adding an additional E-I-S sequence between luciferase and the Sendai virus 5' end of the N gene, see Figure 1, the caption under the figure, as well as the first paragraph of the discussion section on page 2818. The E-I-S sequence comprises "CTTTCACCCCT", see the first paragraph of the first column on page 2814. The RNA transcribed from this sequence inherently possesses the corresponding RNA nucleotides, "CUUUCACCCU". Hasan et al. also anticipate a composition comprising at least  $4.7 \times 10^8$  pfu/ml of the Sendai virus vector of claim 1 in a physiologically acceptable carrier since the viral titers of the recovered virus of the second passage from embryonated eggs ranges between  $2.1 \times 10^9$  to  $8.7 \times 10^9$  pfu/ml, see Table 1 on page 2816. Therefore, Hasan et al. anticipate the invention.

Applicant states that Hasan et al. appears to show that the luciferase gene is inserted 5' to the N gene. Applicant describes the transcription of the described RNA of Hasan et al. and concludes that the luciferase gene of Hasan et al. is actually located 3' to the N gene.

Applicant's arguments have been considered, but are found unpersuasive. The examiner is unable to understand applicant's position because the statement that antigenomic RNA is generated from the plasmid vector is incorrect because it is actually an anti-sense RNA strand that is generated. The reference clearly shows that the luciferase gene is upstream, i.e. 5', to the viral genes, which are present in the order recited in claim 3, see Figure 1 on page 2815.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

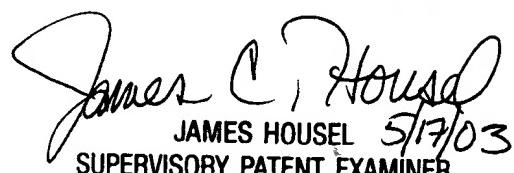
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Shanon Foley  
May 16, 2003



JAMES C. HOUSE  
JAMES HOUSEL 5/17/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600